

### **Remarks**

This Amendment is responsive to the Official Action mailed November 19, 2002 (Paper No. 22). Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully request.

### **Claims**

Claims 10, 11 and 14-19 were pending. Claims 10, 11 and 14-19 stand rejected.

Applicants hereby authorize the Commissioner to charge any additional claim fees required by entry of this Amendment to Deposit Account No. 04-0480.

Claims 10 and 11 have been amended to more clearly recite the present invention. Thus, claims 10, 11, and 14-19 are pending. Support for these amendments to the claims is apparent. Thus, no new matter is added.

### **Claim Objections**

Claim 11 was objected to for reciting "wherein the concentration of concentration of benzoic acid." Applicants have amended claim 11 as suggested by the Examiner to recite, "wherein the concentration of benzoic acid.." Withdrawal of objection is respectfully requested.

Claim 11 was objected to for being in improper dependent form for reciting "paraben" when claim 10, upon which claim 11 depends, recites particular forms of paraben. Applicants have amended claim 11 to recite specific species of paraben as recited in claim 10. Withdrawal of objection is respectfully requested.

### **Rejection Under 35 U.S.C. §112(2)**

Claim 10 was rejected under 35 U.S.C. §112, second paragraph for indefiniteness in reciting the term, "such as." Applicants have amended the claim to no longer recite "such as." Withdrawal of rejection is respectfully requested.

### **Rejection Under 35 U.S.C. §103(a)**

Claims 10, 14, 16 and 18 were rejected as under 35 U.S.C. §103(a) as allegedly being unpatentable over Purohit et al. (U.S. Patent No. 4,966,754). In particular, the Examiner alleged

Purohit et al. (US 4,966,754) taught compositions for preserving cosmetics (Abstract). Purohit et al. taught that methyl and propyl paraben were well known bacteriocidal (toward *S.aureus*) and non-toxic preservatives found in cosmetics (col.1, lines 18-23). Purohit et al. taught that many essential oils, such as basil oil, Fennel sweet oil and active components of essential oil such as estragon (a.k.a., estragole) were antimicrobally effective toward *A. Niger*, *C.albicans*, *S.aureus* and *P.aeruginosa* (col.1, lines 37-64 and col.2, line 62- col.3, line 35/ See 'Table'). Purohit et al. further taught that the preferred amount of essential oil or component thereof should have been present in the composition from 2-5%, while 2% was preferred (col.3, lines 43-47). Purohit et al. disclosed that cosmetics "require[ed] a dermatologically acceptable carrier or vehicle" (col.2, lines 45-50).

Where claim 16 recites 'a medicament to inhibit micro-organism growth' is intended use language which does not materially change the composition. It is noted that the term 'medicament' is a broad term. The Examiner has interpreted 'medicament' to mean any agent which has the potential of exhibiting even a small degree of pharmaceutical benefit. In the instant case, either of methyl paraben or basil oil would possess some medicinal benefit because both inhibited microorganisms which were known in the art to have virulent capabilities such as *S.aureus*. Therefore, the individual constituents would have constituted 'medicament' which inhibited microorganism growth.

Additionally, claim 18 recites 'spray formulation'. The Examiner has given the term it's broadest interpretation, and deemed that any liquid could be sprayed (i.e., placed in a spray bottle and 'sprayed'). Thus, it appears that this claim limits claim 11 to wherein the composition is in liquid form. It is deemed that the essential oils such as basil oil and fennel sweet as disclosed by Purohit et al. were in liquid form and therefore could have been 'sprayed'.

Purohit et al. did not specifically teach a specific combination of basil oil along with preservatives such as methyl or propyl paraben further in combination with a carrier.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each was well known in the art to possess bacteriocidal activity toward *S.aureus*, thereby rendering these constituents as suitable cosmetic preservatives according to Purohit et al. One of ordinary skill in the art would have been motivated to combine antimicrobial agents such as basil oil and methyl paraben for example, in a cosmetic composition in order to achieve an additive bactericidal effect.

The ordinary artisan would have been further motivated to have added a carrier base in order to have formulated a cosmetic composition which could have been easily applied by the consumer. As stated *supra*, Purohit et al. Taught that carriers were 'required' when producing cosmetics.

This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Applicants respectfully assert that Purohit et al. does not motivate one of ordinary skill in the art to combine essential oils such as basil oil with preservatives such as propyl paraben. Indeed, Purohit specifically teaches away from the claimed invention.

The problem addressed by Purohit et al. is the provision of anti-microbial cosmetic compounds which do not irritate the skin to which the cosmetic is applied. Purohit et al. teaches that conventional cosmetics comprise bactericides which are generally synthetic or compounds such as methyl or propyl paraben, Dowicil 200 or various quaternary compounds (see for example, column 1, lines 18-23 of Purohit et al.). Purohit et al. proceeds to describe that such mircorbial agents tend to be, to some extent, toxic and may be dermatologically unacceptable (see column 1, lines 21-29). Purohit et al. addresses this problem by the use of essential oils as a preservative or anti-microbial agent. As taught on column 1, lines 62-65, such oils are "safe, mild and effective preservative agents compatible with conventional cosmetic ingredients such as vehicles or carriers."

Moreover, Purohit et al. teaches that to be effective as an anti-microbial agent, the essential oil or mixture of essential oils must be effective against at least four groups of micro-organisms; molds, yeast, gram positive and gram negatives (see column 1, lines 30-34). Purohit et al. teaches that in its preferred embodiments, the anti-microbial essential oil must be present at a level of about 2% by weight of the total cosmetic composition (column 3, lines 43-46). Even with the preferred blend of oils, Blend X, which Purohit et al. teaches provides optimum anti-microbial properties, at least 2% of the blend is required. As described on column 4, lines 42-56, a clean kill of all four micro-organisms in 72 hours is only achieved at the 2% level of this optimum blend of essential oils. As Blend X is taught to provide the optimum anti-microbial effect, one of ordinary skill in the art would understand that compositions comprising individual

already taught  
they are  
No, they don't

essential oils, or blends other than Blend X, would be less effective than that taught by Purohit et al.

*Concentration only in claim 11*  
In contrast to Purohit et al., the present invention as defined in claims 10, 11 and 14-19 is directed to an anti-microbial formulation which comprises fennel oil or basil oil at a concentration of 0.1%-1%. In other words, the present invention is directed to a concentration in the range of 20-fold to 2-fold less than the concentration of essential oil taught by Purohit et al. to be necessary for effective anti-microbial action. One of ordinary skill in the art would not be motivated by Purohit et al. to use such a low concentration of essential oil--a concentration which Purohit et al. teaches would be ineffective.

Applicants respectfully disagree with the Examiner's assertion that the skilled person would be motivated by Purohit et al. to combine an essential oil with benzoic acid, methyl paraben, ethyl paraben, propyl paraben or butyl paraben. Purohit et al. is directed to the provision of cosmetic compositions in which essential oils are used as preservatives to avoid the problems associated with compounds such as methyl paraben, or benzoic acid, for example, with respect to dermatological acceptance. Purohit et al. explicitly teaches against the use of benzoic acid, methyl paraben, etc. in such compositions. Furthermore, Purohit et al. teaches that the problems associated with the use of benzoic acid, methyl paraben etc. can be solved by the use of at least 2% of essential oils, preferably in the form of Blend X. Thus, one of ordinary skill in the art would receive no motivation from Purohit et al. to combine essential oils, which are taught to be safe and effective as microbial agents, with agents such as benzoic acid, methyl paraben, ethyl paraben, or butyl paraben, which it teaches to be less dermatologically acceptable. No

Finally, even assuming, *arguendo*, that one of ordinary skill in the art could be motivated by Purohit et al. to attempt to combine an essential oil with a conventional preservative, Purohit et al. neither teaches nor suggests that such combinations could be synergistic. As taught in the present Application, combinations of the essential oil and the conventional preservatives were found to have a synergistic anti-microbial effect (see specification pages 11, lines 13-17, lines 20-26; page 12, lines 7-14; and page 13, lines 10-20). Such synergism could not and would not be predicted from the teachings of Purohit et al. For these reasons, Applicants respectfully assert that the present invention is not obvious over Purohit et al. Withdrawal of rejection is respectfully requested.

Claims 10-11 and 14-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Purohit et al. in view of Zimmerman et al. (U.S. Patent No. 5,443,817). In particular, the Examiner alleged,

Claims 11, 15, 17 and 19 are further drawn to wherein the concentration of benzoic acid or paraben is from 0.01% to 1%, wherein this composition is admixed with a pharmaceutically acceptable carrier, wherein the medicament inhibits micro-organism growth, and wherein the formulation is in the form of a spray.

The teachings of Purohit et al. were discussed *supra*, which provided motivation for the combination of oils such as basil oil with preservatives such as propyl paraben to inhibit microorganism growth.

Purohit et al. did not mention wherein an acceptable concentration of methyl or propyl paraben was from 0.01% and 1% of the composition, nor where this particular composition was combined with a pharmaceutically acceptable carrier or wherein the medicament was 'to inhibit micro-organism growth' or wherein the formulation was in the form of a 'spray formulation.' Zimmerman et al. (US 5,443,817) taught a sprayable cosmetic cleansing formulation which contained preservatives such as propyl paraben for protection against microbial contamination (Abstract and col.4, lines 43-62). Zimmerman et al. proposed that "Preservatives are preferably employed in amounts ranging from about 0.01% to about 2% by weight of the composition" (col.4, lines 60-62).

It would have been obvious to combine basil oil and propyl paraben in a cosmetic carrier as discussed *supra*.

One of ordinary skill in the art would have been motivated to have incorporated the propyl paraben in an amount from 0.01% to about 2% into a cosmetic composition comprising a bacteriocidal essential oil such as basil oil in order to afford an effective amount of preservation potential. The ordinary artisan would have had a reasonable expectation that the combination of basil oil and the preferred concentration of preservative would have afforded good protection against bacterial contamination, which would have in turn produced a cosmetic product which was safer for consumers.

It is noted that 0.01%-2% (disclosed range) overlaps with the claimed range of 0.01%-1%. Thus, the claimed range is obviated by the range as disclosed by Zimmerman et al. (See MPEP § 2144.05).

Where claim 16 recites 'a medicament to inhibit micro-organism growth' is intended use language which does not materially change the composition.

Additionally, claim 18 recites 'spray formulation'. The Examiner has given the term it's broadest interpretation, and deemed that any liquid could be sprayed (i.e., placed in a spray bottle and 'sprayed'). Thus, it appears that this claim limits claim 11 to wherein the composition is in liquid form. It is deemed that the essential oils such as basil oil and fennel sweet as disclosed by Purohit et al. were in liquid form and therefore could have been 'sprayed'.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants traverse this rejection. For the reasons discussed above, the primary reference of Purohit et al. does not render the present invention as obvious. Zimmerman et al. fails to teach or suggest which is lacking in Purohit et al, namely, a suggestion to combine essential oils, which are taught to be safe and effective as microbial agents, with agents such as benzoic acid, methyl paraben, ethyl paraben, or butyl paraben, which it teaches to be less dermatologically acceptable, and to do so in concentrations that are 20-fold to 2-fold less than that which Purohit et al. teaches is necessary for effective anti-microbial action. One of ordinary skill in the art would not be motivated by Purohit et al. to use such a low concentration of essential oil--a concentration which Purohit et al. teaches would be ineffective. As explained above, Purohit et al. explicitly teaches away from the present invention. Thus, one of ordinary skill in the art would not be motivated to combine Purohit et al. with Zimmerman, and if the two cited references were combined, the ordinary artisan would still not arrive at the present invention. Withdrawal of rejection is respectfully requested.

**FEE DEFICIENCY**

- ☒ If an extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time; The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 04-0480.

**and/or**

- ☒ If any additional fee is required for consideration of this paper, please charge Account No. 04-0480.

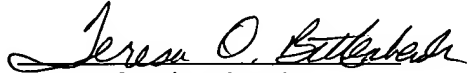
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Group Art Unit: 1651

**Closing Remarks**

Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Teresa O. Bittenbender".

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**Detail of claim amendments**

10. (Three Times Amended) A formulation comprising a combination of at least one plant oil chosen from oils of fennel, basil, or active ingredients thereof together with at least one of the group comprising benzoic acid, methyl paraben, ethyl paraben, propyl paraben or butyl paraben, wherein the active ingredients of the plant oils are trans-anethole, fenchone or estragole, and the concentration of fennel oil or basil oil or active ingredient thereof[therof] is between 0.01% to 1%, wherein said formulation is used as a micro-organism inhibitor [such as a food preservative].

11. (Three Times Amended) A formulation as claimed in claim 10 wherein the concentration [of concentration] of benzoic acid, methyl paraben, ethyl paraben, propyl paraben or butyl paraben is from 0.01% to 1%.



**Claims following entry of amendment mailed March 19, 2003**

10. (Three Times Amended) A formulation comprising a combination of at least one plant oil chosen from oils of fennel, basil, or active ingredients thereof together with at least one of the group comprising benzoic acid, methyl paraben, ethyl paraben, propyl paraben or butyl paraben, wherein the active ingredients of the plant oils are trans-anethole, fenchone or estragole, and the concentration of fennel oil or basil oil or active ingredient thereof is between 0.01% to 1%, wherein said formulation is used as a micro-organism inhibitor.

11. (Three Times Amended) A formulation as claimed in claim 10 wherein the concentration of benzoic acid, methyl paraben, ethyl paraben, propyl paraben or butyl paraben is from 0.01% to 1%.

14. (Twice Amended) The formulation according to claim 10 wherein the formulation is in combination with a pharmaceutically acceptable carrier.

15. (Twice Amended) The formulation according to claim 11 wherein the formulation is in combination with a pharmaceutically acceptable carrier.

16. A medicament to inhibit micro-organism growth comprising a formulation as claimed in claim 10.

17. A medicament to inhibit micro-organism growth comprising a formulation as claimed in claim 11.

18. A formulation as claimed in claims 10 in a spray formulation.

19. A formulation as claimed in claim 11 in a spray formulation.